

REMARKS

It is respectfully requested that the present Response be entered into the Official File in view of the fact that the Response automatically places the application in condition for allowance. Alternatively, if the Examiner continues with the rejections of the present application, it is respectfully requested that the present Response be entered for purposes of an Appeal.

Status of the Claims

Claims 1-3 are now presently pending in this application. No claims are being amended, added, or canceled in the present Response.

Reconsideration of this application is respectfully requested based on the following remarks.

Substance of the Interview

Applicants thank the Examiner for her time, helpfulness and courtesies extended to Applicants' representative during the Interview of December 29, 2010. The assistance of the Examiner in advancing prosecution of the present application is greatly appreciated. In compliance with M.P.E.P. § 713.04, Applicants submit the following remarks.

The Interview Summary form amply summarizes the discussions at the Interview. Applicants' representative and the Examiner discussed in detail the Rule 132 Declarations of record and the outstanding Office Action. The Examiner's comments are repeated below in addressing the rejection for obviousness.

Rejections under 35 U.S.C. § 103(a)

Claims 1-3 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Misaki '996** (U.S. Patent No. 4,765,996) in view of **Kwak '997** (U.S. Patent No. 6,402,997), **Nanbu '675** (U.S. Patent No. 6,074,675) and **Tamaki '462** (U.S. Patent No. 6,436,462) (Office Action, pages 2-8). Also, the reference of **WO '065** (WO 2008/140065) is provided as evidence. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated herein.

The Present Invention and Its Advantages

The present invention is directed to iron-enriched and vitamin-enriched rice or barley, wherein the rice grains or barley grains are coated with an emulsifying agent-coated iron salt composition (e.g., claims 1 and 3) or coated with a polyglycerol fatty acid ester (claim 2). Also, the pending claims recite that the iron salt has an average particle diameter of 0.05 to 0.8 μm (claims 1 and 3) or the range of 0.05 to 0.5 μm (claim 2). Further, as recited in claims 1 and 3, the emulsifying agent is an enzymatically decomposed lecithin.

The present invention achieves unexpectedly less loss of, for example, vitamins and minerals upon storage of the rice or barley. As submitted previously with the Amendment of September 27, 2010, the Rule 132 Declaration establishes unexpected results for the present invention. As shown in Tables I-III, the Rule 132 Declaration of record shows better retention of vitamins and minerals after washing, after cooking, and during long term storage of the non-cooked product.

Applicable U.S. Case Law

The obviousness inquiry is decided as a matter of law, based on four general factual inquiries as explained in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966), and reaffirmed in *KSR Int'l, Inc. v. Teleflex, Inc.*, 550 U.S. 398, 406-07 (2007).

Also, regarding the *Graham* factor of evaluating any evidence of secondary considerations, M.P.E.P. § 2145 clearly sets forth that rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu*, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995), or by way of an affidavit or declaration under 37 C.F.R. § 1.132, e.g., *Soni*, 34 USPQ2d at 1687; *In re Piasecki*, 223 USPQ 785, 789-90 (Fed. Cir. 1984).

Evaluating the Evidence of Secondary Considerations To Date, and One of Ordinary Skill in the Art Would Not Combine the Cited References

The *Graham* factors weigh in Applicants' favor, and a proper rationale has not been used to reject the disputed claims. Regarding the *Graham* factor of ascertaining the differences between the prior art and the claims at issue and evaluating any evidence of secondary considerations, Applicants previously submitted two Rule 132 Declarations. As mentioned above, the experimental data shows unexpected results for the claimed invention. Specifically, the inventive examples ("Enriched Rice 2" and "Enriched Rice 4") show the better retention of vitamins and minerals versus the comparative examples ("Enriched Rice 1" and "Enriched Rice 3").

Further, by reproducing Example 5 of the cited primary reference of Misaki '996, Applicants have reproduced the closest prior art example that exists (which is Enriched Rice 1). In this regard, a comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. *See* M.P.E.P. §§ 716.02(b) and 716.02(e); *see also In re Fenn et al.*, 208 USPQ 470 (CCPA 1981). Enriched Rice 2 replaces the aqueous dispersion containing ferric pyrophosphate of Misaki '996 with the claimed emulsifying agent-coated iron salt composition A (Example 1 described at page 18 of the specification, or pages 3-4 of the Rule 132 Declaration). Thus, a proper comparison can be made by the skilled artisan between Enriched Rice 1 and Enriched Rice 2, and any differences between the two examples can be attributed to the claimed emulsifying agent-coated iron salt composition having the enzymatically decomposed lecithin.

Similarly, Enriched Rice 3, which is a modification of Example 8 of the present specification, is also a proper comparative example. It is worth noting that an applicant may compare the claimed invention with prior art that is closer to the invention than the prior art relied upon by the Examiner. *See In re Holladay*, 199 USPQ 516 (CCPA 1978). Enriched Rice 4 is the inventive example and is the same as Enriched Rice 3, except the aqueous suspension containing ferric pyrophosphate was replaced with the claimed emulsifying agent-coated iron salt composition. Thus, a proper comparison can be made between Enriched Rice 3 and

Enriched Rice 4, and any differences between the two examples can be attributed to the claimed emulsifying agent-coated iron salt composition having the enzymatically decomposed lecithin.

Thus, Applicants traverse the present rejection for reasons of record.

However, in the current Office Action, the Examiner states that the Declarations are still insufficient. And during the mentioned Interview, the Examiner stated that Applicants should test further and/or all types of inventive embodiments, including other particle diameters of the enzymatically decomposed lecithin; different types of rice and/or barley; different types of iron salts; different types of hydrogenated oils; different types of enzymatically decomposed lecithins; different types of polyglycerol fatty acid esters; etc.

In response to the Examiner's required testing of other embodiments, Applicants respectfully submit that the Examiner has failed to provide any technical or scientific evidence showing that the recited features would not work (e.g., that another hydrogenated oil would not work for Enriched Rice 2 and 4). The standard of preponderance of the evidence for patentability has not been met. *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992). Thus, the burden of proving patentability in this regard has not shifted to Applicants.

The Examiner also requested testing rice that is uncoated versus being coated with the emulsifying agent-coated iron salt composition and vitamins. However, unexpected results have already been shown with respect to the claimed enzymatically decomposed lecithin, and it is not clear as to why an uncoated embodiment is needed. Testing uncoated rice is not within the scope of the claims.

Regarding the assertion that all ingredients have to tested to be commensurate in scope, it appears that the Examiner is relying upon M.P.E.P. § 716.02(d) to state that the unexpected results must be commensurate in scope with the claims. However, this part of the M.P.E.P. refers to *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980), *In re Peterson*, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) and *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983). Such case law deals with numerical ranges. Further, M.P.E.P. § 716.02(d)(I) refers to testing of a narrower range to support the patentability of a broader claimed range; M.P.E.P. § 716.02(d)(II) refers to criticality of a claimed range. Thus, this part of the M.P.E.P. refers to numerical ranges, and does not refer to,

e.g., every genus or subgenus that is recited in a particular claim (e.g., hydrogenated oils for the present claims; etc.). It is believed that the Examiner's request is improper.

Further, the Examiner is requiring a burdensome and enormous amount of testing by Applicants. While U.S. case law holds that testing should be commensurate in scope with the claims, such case law does not require all sorts of testing. For instance, as stated in M.P.E.P. §2145: "When considering whether proffered evidence is commensurate in scope with the claimed invention, Office personnel should not require the applicant to show unexpected results over the entire range of properties possessed by a chemical compound or composition. See, e.g., *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Further, it is not clear as to, e.g., all types of rice have to be tested.

Also regarding testing as being commensurate in scope request, Applicants note that, coupled with the submitted Rule 132 Declarations, the experimental data as present in the specification should be considered. *In re Soni*; *supra*. Specifically, Applicants test Inventive Products I-L as can be seen from Table I on page 24 of the specification, which clearly have superior and unexpected results versus Comparative Products M-O. Further, the inventive products test different ingredients that also fall within the scope of the pending claims. For instance, different polyglycerol fatty acid esters are used in the Examples, wherein Example 3 uses "Dispersion C", and the polyglycerol fatty acid ester of pentaglycerol monomyristate. Example 4 uses "Dispersion D", and the polyglycerol fatty acid ester of pentaglycerol trioleate. These Dispersions are later used for Enriched Rice I-L.

But given the Examiner's comments during the Interview, Applicants herein enclose another Declaration under 37 C.F.R. § 1.132 (by Noboru Sakaguchi). The enclosed Rule 132 Declaration is the opinion by one of ordinary skill in the art, and how other, e.g., hydrogenated oils would give the same or substantially similar results as the specific hydrogenated oil that was actually, previously tested. As stated in M.P.E.P. § 2145, rebuttal evidence may include evidence of the state of the art, the level of skill in the art, and the beliefs of those skilled in the art.

As stated in the currently attached Rule 132 Declaration, the skilled artisan would review the experimental data of record (whether from declarations or in the specification) and understand that such data is sufficient to show unexpected, superior results for the scope of the claims, and there is enough data to eliminate any scientific uncertainty.

Examiner also stated during the Interview that Applicants need to claim the unexpected results of better residual activity of the vitamins and minerals as shown **Tables I, II and III** in the Rule 132 Declarations. However, in response, Applicants respectfully submit that this is a legally incorrect position. The Examiner is respectfully reminded of the legal precedent, *In re Merchant*, 197 USPQ 785, 788 (C.C.P.A. 1978), concerning objective evidence, as follows (*emphasis added*):

Finally, the solicitor repeats the objection voiced by the examiner that the declaration is irrelevant because the claims specify neither the unexpected result nor the “features” that produce that result. *We are aware of no law requiring that unexpected results relied upon for patentability be recited in the claims.* The “features” referred to by the examiner are the conditions of pressure, feed rate, and reactor retention time for the commercial operation described in the declaration. We are equally unaware of any law requiring that commercial production parameters be claimed. Moreover, the “feature” responsible for appellant’s unexpected results is recited in the claims, viz., “substantially anhydrous.”

(Applicants’ emphasis added.) Thus, the obtained properties/results such as a lower percent of loss of vitamins after washing do not have to be claimed. This is especially true when the claimed enzymatically decomposed lecithin is already recited and, as proven by the experimental evidence of record, leads to the improved properties.

Based on the above, it is believe that the instant rejection is improper, and more so, that unexpected results to date are sufficient to rebut any asserted *prima facie* case of obviousness. Thus, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

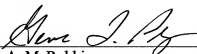
When all evidence is considered anew, it is believed that the instant rejection has been overcome. A Notice of Allowability is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Registration No. 48,501, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: January 28, 2011

Respectfully submitted,

By  448,501
Craig A. McRobbie
Registration No.: 42874
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, VA 22040-0747
703-205-8000

Attachment: Declaration under 37 C.F.R. § 1.132